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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,244	09/21/2001	Tony W. Ho	2831.2003-000	4326

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EXAMINER	
LANKFORD JR, LEON B	
ART UNIT	PAPER NUMBER
1651	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/960,244	HO ET AL.	
	Examiner	Art Unit	
	Leon Lankford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,19-21,25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,19-21,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The suspension of this case has expired. The finality of the office action of 11/30/2005 has been withdrawn.

The amendment of 12/13/2005 has been entered. It is suggested that in response to this action that applicant submit a new version of the claims because a line bisecting the page mars this faxed claim set.

On 9/13/2006, an interview was conducted with the examiner of record, his SPE and Interference Specialist Tsang. The interview is summarized in applicant's letter of 10/4/2006. On 1/4/2007, the examiner and Dr Murray, applicant's representative conducted an interview further discussing the submission of 10/4/2006. In the interview of 1/4/2007, Dr Murray was informed that a non-final rejection was prepared and ready for mailing however Dr Murray requested that the action be delayed until further possible discussion. No fruitful discussions occurred therefor the action is now being issued.

In the interview of 1/4/2007, the examiner indicated that the below rejection would be brought forth by the office. The examiner informed Dr Murray that the claims did not appear to distinguishable over the putative prior art and that the 102(e) rejection below would need to be made. It was also suggested to Dr Murray that much of what was submitted in the letter of 10/4/2006 seemed to be evidence and/or opinion and as such would have to be properly submitted in a rule 132 declaration. Further, it was noted that the arguments failed to clearly make the case that claimed cells were not anticipated by the cells disclosed in the '037 patent.

Applicant's further requested an interview with SPE Michael Wityshyn which is summarized in the attached form 413.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14, 19-21 & 24-25 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Furcht et al (7015037).

Furcht et al disclose a population of cell which co-express CD49c and CD90 and is derived from human bone marrow. Furcht suggests that the population can be pure or essentially pure and claims it as such. Furcht is directly silent on doubling rate les than about 30 hours but does disclose and claim a doubling rate of about 36 hours. Both the disclosure of the instant application and the Furcht patent use the relative term "about" to define their doubling times and in that the office is tasked with giving the claim language its broadest reasonable interpretation, the ranges are considered to overlap absent argument or evidence to the contrary. As such, given that Furcht discusses a pure cell population and since the doubling rates are considered to overlap,

a holding of anticipation is required. Further while Furcht is silent on some of the limitations of the dependent claims, as the evidence suggests that the cell populations are the same, those properties must be inherent to the cells and population disclosed by Furcht.

It should also be noted that doubling rate is akin to an intended use of the claimed population as it is a measure of a process of use of the product, i.e. the population. The doubling rate of identical cells or populations would be an inherent property of the cells or population and as msuch if the cells are the same the doubling rates would necessarily be as well. Doubling rate is a product of the culture conditions as is discussed in the Dean declaration in the Furcht patent application and acknowledged in the instant specification in the second paragraph on page 8 "The doubling time of the cells of the invention can be varied depending on, for example, the density of the cells in culture (e.g., 100 cells/cm2) and/or the concentration of oxygen employed to culture the cells (e.g., a low oxygen concentration such as about 5% oxygen)." As such, given that the cells of Furcht are isolated from the same tissue, in a like manner to the isolation of the instant application, and co-express express CD49c and CD90 the cells would appear to be the same and the doubling rate an inherent property. It should be further noted that since applicant's claims allow for up to about 9% of an unidentified cell type in their population, the doubling rate holds less meaning in that it does not serve to distinguish the cell population (or really the cells *per se)* from cells taught in the prior art. Applicant is claiming the cell doubling rate of an entire

population of cells wherein a significant portion of the cells are not identified. The doubling rate could be greatly skewed by the presence of non-novel fast or slow doubling cells and as such it is hard to consider doubling rate a defining characteristic in the instant application. Further the Dean declaration filed during the prosecution of '037 sets forth data supporting the argument that the cells in '037are the same as those instantly claimed when cultured under the same conditions. In the Dean declaration, the doubling rate from 7/30/04 to 8/3/04 was calculated using Applicants' formula to be 32, which is close to the instantly claimed doubling rate of "less than about 30 hours". The doubling rate from 8/3/04 to 8/6/04 was calculated to be 18, which is clearly less than about 30 hours. After 8/6/04, the doubling rate increases considerably above 30 hours. Therefor, the doubling rate claimed does not distinguish the claimed invention from the cell population taught by Furcht.

Applicant has pointed out that Furcht patent, though discussing pure populations, does not necessarily depict a population of cells where at least about 91% of the cells coexpress CD49c and CD90. Applicant argues that Figures 2 and 4 of the Deans Declaration depict expression of CD49c (upper right frame) and CD9O (lower right frame) on the surface of cells; separate measurements of the expressions arethat measured and that does not necessarily depict greater than 91% co-expression. Applicant argues in particular, where 91% of the cells express CD49c and, separately, 91% of the cells express CD90, co-expression of these factors may be as low as 83% (0.91 x 0.91 = 0.83). It must be noted that the Furcht patent does not suggest that there are

greater than about 9% of other cells in their purified population and thus a holding of anticipation is necessary.

Regarding the specific evidence in the preceding paragraph, Applicant is correct that this showing *may* not show 91% co-expression however the evidence as such shows that greater than about 91% of the cells co-express CD49c and greater than about 91% co express CD90 and that allows for 91% coexpression. In fact, the co-expression should be considered about 91% coexpression in the absence of any teachings at all that there are "contaminating" cells in the population which either express only CD49c or CD90 which would be necessary to adapt applicant's arguments that the percentage was less than about 91%. Further, as aplicant's claims require "more than about 91%" and the exemplified Furcht purity is somewhere between 83 and about 91%, a holding of anticipation is proper.

Nevertheless, even if a holding of anticipation was inaccurate because Furcht did not achieve the same purity, the claimed cell population would have been rendered obvious by the cell population of Furcht because, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. See MPEP 2100: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between

25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); >see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.");< ** In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). In the instant case, at the very worst case scenario, the prior art teaches about an 83% coexpression of the desired cells containing the identified markers and it would've been well within the purview of the skilled artisan at the time the invention was made to further purify the co-expressing cells to eliminate undesired cells through immunoselection. Therefore the claimed population was at least *prima facie* obvious over the population of the Furcht patent absent evidence to the contrary.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not Applicants' seroconversion rates differ and, if so, to what extent, from that discussed in the references. Therefore, with the showing of the references, the burden of establishing non-obviousness by objective evidence is shifted to Applicants. Significantly, applicant provides no factual evidence whatsoever to refute the holding of anticipation or obviousness. Note specifically that on the current record the only way of overcoming such a clear holding of anticipation is factual proof that the rejection is in error. *See* MPEP § 2112, disclosing that once a proper holding of anticipation is made, the burden shifts to applicant to demonstrate an unobvious difference between the claims and the prior art. *See also, In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) ("the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product"). Because applicant has not demonstrated any difference between the claimed products and the prior art products, the rejection of record clearly must be maintained. Futher MPEP 2112 states:

> [T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on `inherency' under 35 U.S.C. 102, on `prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product - by - process claims. Quoting *In re Fitzgerald*, 619 F. 2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (itself quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 - 34 (CCPA 1977)).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Lankford whose telephone number is 571-272-0917. The examiner can normally be reached on Mon-Thu 7:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leon B Lankford Jr
Primary Examiner
Art Unit 1651